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## Resistance and Consistent: Access to Medicines and Patent Law Reforms in India and China

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## INTRODUCTION

The globalization of patent through the forum of the Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) has triggered heat debated on the role of patent in public interest safeguarding including access to medicines in developing countries. On the one hand, TRIPS has presented within a single undertaking scenario of WTO as a binding international law instrument. Such one-size-fits-all approach has triggered large debates around the national discretion in patent laws. On another hand, TRIPS also contains flexibilities, and which remain an area of bargaining among different influencing powers including state and non-state actors. In addition, with more and more member states are to be bound by TRIPS through law reform at national level, the debates at international level has had extension to national law process.

The paper starts with reviewing the debates on patent in access to medicines in the context of globalization of TRIPS regime. It then looks at the issue of resistance related to patent theories, mechanism and the linkage with social movement during law reform processes. Accordingly, the 2005 revision of Patent Act in India and the 2008 revision of Patent Law in China are chosen as the backdrops for comparison. The choice of patentability doctrine and the exceptional clauses to promote research use would be the major aspects of comparison, both having been influenced by civil society actions at different degrees in both countries. The paper intends to draw the conclusions that while strong technocratic influences remain, both countries' law makers have started walking out of the closed discourse of patent law reform via interacting with societal concerns in the context of improving access to medicines.

## BACKGROUND: DEBATES ON ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY

The past two decades have marked the significant debates on the role of intellectual property, especially patent, on accessibility of affordable medicines in resources limited settings following the establishment of TRIPS under WTO in 1992. Essentially, the concerns over the

expansion of patenting on medicines through international law are largely due to the fact that while non-discriminatory patent on all products are required, pharmaceutical products are no longer exemptible from patenting subject matters under national laws. The 20 years market monopoly associated with patent would guarantee the dominant position of pricing and marketing by small groups of multinational pharmaceutical companies.

Despite the rigid globalization of patent regime in the form of a binding international law, TRIPS does contain flexibilities for national patent laws. Those flexibilities allow a country to determine the specific patentability criteria on a subject matter, making exceptions on the ground of public interests or research needs, set up ex post mechanism, or making unauthorized use of a patent through compulsory license. Nonetheless, the extent to which flexibilities could be used in full is more a matter of national capacity and bargaining between legislators and influence groups in the law reform process.

Three features could be summarized in relation to the debates around TRIPS in this regard. Firstly of all, TRIPS reinforced the hard-law regime of patent in international law system. In contrast to WIPO treaties, the non-voluntary and enforceable natures have substantively changed the nature of intellectual property issues from a domestic choice into a binding international law obligation.

Secondly, TRIPS has triggered the fundamental forum shift of discussions on intellectual property law. TRIPS combine intellectual property issues with trade liberalization. Such change also implies the scope of debates to be developed from technicality oriented ones into broader context.

Thirdly, the evolution of TRIPS and its implementation is also a process of power structure change at both international and national levels. At the international level, the introduction of TRIPS into WTO had been considered as a result of 'neo-liberal agenda of global

governance’.<sup>1</sup> In the past decades, such hegemonic structure has started shifting with emerging economics taking more stages in policy discussions. While this phenomenon has yet prominent in the context of patent law, the interruption of non-state actors especially international NGOs has played notable role in the international debates and negotiation.<sup>2</sup>

## SITES OF RESISTANCE AND PATENT LAW REFORM

The resistance to patent could be understood from different levels, including those within patent system and those from outside.

### *Theoretical Uncertainty*

From theoretical perspectives, the incentive for innovation argument has been considered as the ‘strongest and most widely appealed’<sup>3</sup> utilitarian justification for patent. Nonetheless, since it is rooted in a narrow interpretation of social welfare from utilitarian economic tradition, and function in a way that, ‘by slowing down the diffusion of technical progress it ensures that there will be more progress of diffuse’,<sup>4</sup> it is considered as paradoxical.

In the context of health, on the one hand, researches have considered that patent system is ‘much more suited to pharmaceutical’<sup>5</sup> industry. On another hand, other groups of researches have rather argued the Tragedy of Anti-commons<sup>6</sup> that the privatization of biomedical research with patent has brought the consequence of stifling innovation.<sup>7</sup>

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<sup>1</sup> May, C. & Sell, S K., *Intellectual Property: A Critical History* (London, Lynn Rienner Publishers, 2006), p. 19. See also, Sell, S K., *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, 2003), pp. 1-3.

<sup>2</sup> Duncan, M, ‘The Role Of International NGOs In The Intellectual Property Policy-Making And Norm-Setting Activities Of Multilateral Institutions’, 82 *Chicago-Kent Law Review*, (2007), p.1369.

<sup>3</sup> Hettinger, E C., ‘Justifying Intellectual Property’, 18/1 *Philosophy & Public Affairs* (Winter 1989), p.47.

<sup>4</sup> Id.

<sup>5</sup> Macdonald, S., ‘Exploring the Hidden Cost of Patents’, in Drahos, P. & Mayne, R. eds. *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan, 2002), p. 13-39.

<sup>6</sup> Heller, M. A., ‘The Tragedy of Anticommons: Property in the Transition from Marx to Market’. 111(3) *Harvard Law Review* (1998), pp. 621-688.

<sup>7</sup> Heller, M. A. & Eisenburg, R. S., ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’. Vol 280, (footnote continued)

### *Excessive Patenting as Controversy*

The second level of the resistance lies on the fact of overly resorting to patent protection for the purpose of maintains market competitiveness and monopoly.

From the pharmaceutical industry perspective, secondary patent filing has been considered as the key in order to ‘extent patent protection beyond the basic patent term for as long as possible’,<sup>8</sup> so that generic competition could be prevented.<sup>9</sup> The ever-greening and patent thicket effects of secondary patent would firstly result in a late introduction of generic competition which would affect the possibility of reducing market price of medicines and increasing affordability for developing countries. In addition, it would also increase the cost and burden of conducting follow-up R&D by others.

### *A Touch on Social Change and Role of NGO*

The internal struggles of patent regime have also been mixed with the external interruption from the national and international movement on access to medicines. The more than a decade NGO movement on access to medicines has been part of the phenomenon of looking at patent as a matter of political economy. Such non-specialist engagement has been argued as a part of politicization of intellectual property due to its increasing values in the knowledge-based society.<sup>10</sup> Accordingly, in resisting the globalization of patent regime through TRIPS as a result of power, the NGO movement on access to medicines sets the claims for public health primacy as a tactic in challenging the welfare effects that narrowly embedded in the logic of TRIPS.<sup>11</sup>

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*Science*, (1998), pp. 698-701.

<sup>8</sup> Id. p.3.

<sup>9</sup> Id.

<sup>10</sup> Haunss, Sebastian. *Conflict in the Knowledge Society: The Contentious Politics of Intellectual Property*. Cambridge University Press (2013), p.3.

<sup>11</sup> Id. p. 173-174.

At the international level, international NGO plays different roles in the international negotiations on intellectual property,<sup>12</sup> with different approaches depending on its focuses and objectives.<sup>13</sup> At national level, such involvement is extended to the relationship between international NGO and national social movement, and the relationship between NGO and industrial in the law reform lobby.

## **SETTING THE SCENE FOR COMPARISON: PATENT LAW REFORM IN CHINA AND INDIA**

The rationale of choosing India and China for comparison lies on a number of elements. Firstly, both countries as emerging economies have been recognized as bearing comparatively stronger R&D and manufacture capacities among developing countries. In the field of health, India and China are among the major exporting countries of active pharmaceutical ingredients, with India also as major exporter of generic formulation of medicines.

Secondly, both countries have been undertaking patent law reform in recent years, with India's amended Patent Act entered into force in 2005 and China's third amendment of Patent Law entered into force in 2008. Both law amendments were done in fulfilling obligations of TRIPS, but also contain unique characters respectively that have direct link to the issue of access to medicines. Thirdly, while both countries share different policy environment of NGO movement, civil society however has played a visible role in patent law reform with different strategies.

Based on the above rationales, the research could posit the comparison against the background of the patent law reforms of China and India. The micro level of comparison includes the design of patentability and research exception, and the civil society involvement in patent law reform.

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<sup>12</sup> Ref. Duncan, M, 'The Role Of International NGOs In The Intellectual Property Policy-Making And Norm-Setting Activities Of Multilateral Institutions', 82 *Chicago-Kent Law Review*, (2007), 1369-87.

<sup>13</sup> Id.

## PATENT REFORM AND ‘WAR’?: CASE OF INDIA

India has been seen as a pharmacy for developing world with 67% of its generic pharmaceutical products exported primarily to developing countries.<sup>14</sup> With the India Patent Act 1970 amended and entered into force in 2005, however, the generic production in India has been facing challenges as generic drug development would become more troublesome with the enforcement of product patents on pharmaceuticals. On another hand, after about three decade of rapid development, India generic pharmaceutical sector has started shifting the strategic intent and seeking more patent protection both in India and overseas.<sup>15</sup>

From the point of industry and market scale, it has been observed that India’s pharmaceutical market consists of a large number of small firms.<sup>16</sup> Among about 20,000 companies, there are around 270 are research-based.<sup>17</sup> Generic industry made India the world’s leading pharmaceutical producer, sharing 22% of the global generic production.<sup>18</sup> Such level of productivity also made India the country where generic medicines overturn the multinational brands in the domestic market.<sup>19</sup>

### *Patent Law Evolution and the Impact on Generic Pharmaceutical Development*

The evolution of Patent Act in India has been seen as a successful case of using patent system to generate domestic industry development.<sup>20</sup> Patent system was first introduced to Indian under the British colonization, including the product patent on pharmaceuticals. After independence, the concern of strong dependency on importation for pharmaceutical products and high price of medicines has played an important role in triggering the enactment of Patent

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<sup>14</sup> Bazzle, T., ‘Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India’s Patent System and Essential Medicines’, 42 *Georgetown Journal of International Law* (2011), p. 785.

<sup>15</sup> Kuanpoth, J., *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future*, (Cheltenham, Edward Elgar, 2010), p.129.

<sup>16</sup> *Id.* p.127.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Mueller, J M., ‘The Tiger Awake: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation’, 68 *University of Pittsburgh Law Review* (2006), p.533.

<sup>20</sup> Cullet, P., *Intellectual Property Protection and Sustainable Development* (New Delhi, LexisNexis, 2005), p.75.

Act 1970.<sup>21</sup> The Patent Act 1970 has thus been considered as an essential ‘driver of three decades of growth in the domestic pharmaceutical industry’.<sup>22</sup> As the law created sufficient spaces for generic actors to imitate, the India companies also rapidly developed with extensive skills with technologies,<sup>23</sup> and moving from concentration on production of active pharmaceutical ingredient toward formulation production and exportation.<sup>24</sup>

In 1995, India joined WTO with a transitional period in complying with TRIPS.<sup>25</sup> One of the key spaces India gained from this period is keeping the ability of excluding product patent on pharmaceuticals, despite the need to gradually amend its patent law in order to enforce the product patent upon the expiration of the transition.

During the transition period, India established the mailbox mechanism under the 1999 amendment of Patent Act, partly as a result of two disputes brought by US and European Community respectively to WTO.<sup>26</sup> The mailbox mechanism obliged India to receive patent applications concerning pharmaceutical products without having to conduct substantive examination before the end of the transitional period. At the same time, quasi-patent market exclusivity would be granted to the applicants.<sup>27</sup>

The most recent amended Patent Act aiming for full TRIPS compliance entered into force in 2005, from which point the applications received in the mailbox system have started being examined substantively. The implementation of the Patent Act 2005 has a number of significances and has put India under the spotlight of a controversial patent war over

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<sup>21</sup> Kapczynski, A., ‘Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector’, *Vol. 97 Columbia Law Review* (2010), p.1576.

<sup>22</sup> *Id.*, p.1577.

<sup>23</sup> *Id.*, p.1578.

<sup>24</sup> *Id.*

<sup>25</sup> According to Art 65.4 of TRIPS, if a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (1 January 1995), it had up to 10 years to introduce the protection. But for pharmaceutical and agricultural chemical products, the country had to accept the filing of patent applications from the beginning of the transitional period, though the patent did not need to be granted until the end of this period. *See also*:

[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm)

<sup>26</sup> *US vs. India - Patent Protection of Pharmaceutical and Agricultural Products*, WT/DS50/AB/R, December 1997; *European Community vs. India on Patent Protection of Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R, August 1998.

<sup>27</sup> Mueller, J M., ‘The Tiger Awake: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation’, *68 University of Pittsburgh Law Review* (2006), p.519.



pharmaceuticals. Firstly, Patent Act 2005 has a number of innovative provisions in defining patentability related to pharmaceuticals, with the most known Section 3(d) excluding all derivative forms of a known molecule from being patentable unless significant improvement of efficacy could be proved.

Secondly, after the implementation of Patent Act 2005, India has had the first compulsory license issued on a cancer drug with Bayer as the original patent holder.<sup>28</sup> Although compulsory license on pharmaceuticals has been used in many other countries, the first compulsory license in India on pharmaceutical still stirred a fear of threat to the multinational companies, due to the strong generic capacity in India who has already occupied considerable competitive advantages in the global pharmaceutical market.

Thirdly, the effect of Patent Act 2005 has triggered intensive concern from a global network of stakeholders. This is partly due to India's large scale of generic exportation to developing countries with low cost and good quality medicines. In this sense, public health activists at international levels and civil society groups shared the concerns on the impact on the future access to affordable quality medicines in developing countries if the ability of generic production in India would thus be restricted.

In addition, the changing face of India generic industry as a whole has also added one more level of complexity. After decades of growth in revenue and capacity, a number of India generic pharmaceutical companies have moved towards research-based, and aiming for better international market share through resorting to patent. It has also been observed that many of the R&D interests of India companies are targeting developed countries market rather than India domestic.<sup>29</sup>

### *Implication of Sec. 3 (d) of India's Patent Act on Health Innovation*

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<sup>28</sup> The Hindu, Natco Pharma wins Cancer Drug Case, March 4, 2013, available at:

<http://www.thehindu.com/business/companies/natco-pharma-wins-cancer-drug-case/article4475762.ece>

<sup>29</sup> Kapczynski, A., 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector', *Vol. 97 Columbia Law Review* (2010), p.1584.

One of the innovative and yet almost the most controversial provisions in the current Patent Act of India is Section 3(d) and its explanation notes. Essentially, ‘the mere discovery of a new form of a known substance’<sup>30</sup> would not be considered as patentable. The Patent Act provides an explanation notes underneath the main clause, specifically using pharmaceutical as an example. Accordingly, ‘salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.’<sup>31</sup>

The provision precisely concerns the common strategy used among multinational pharmaceuticals, in which patent life gets prolonged through ever-greening effect of secondary patenting. Therefore, it is not surprising when Section 3(d) started triggering severe controversies.

Such tension has been amounted into a series of cases involving patent opposition, patent invalidation, and patent re-examination, in which multinational pharmaceutical companies started questioning the legality and legitimacy of this provision after failing to get patent granted on their medicines. Among the other cases, the rejection on Novartis’s patent application for its drug Gleevec treating leukaemia has triggered the greatest attention.<sup>32</sup> Essentially, patent under dispute is a beta crystalline form of imatinib mesylate, which is the key active ingredient for leukaemia treatment. In the final ruling by the Supreme Court of India, the narrow interpretation on the efficacy in the sense of ‘therapeutic’ efficacy in human body was upheld.<sup>33</sup> The decision has been considered as having significant public health

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<sup>30</sup> Section 3(d), India, Patent Act, amended up to 2005.

<sup>31</sup> Section 3(d), Explanation, India, Patent Act, amended up to 2005.

<sup>32</sup> IP-Watch, ‘Inside Views: The Judgement in Novartis v. India: What the Supreme Court of India Said’, April 4, 2013, available at: <http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/>,

<sup>33</sup> Ref. CIVIL APPEAL Nos. 2706-2716 OF 2013, Novartis vs. Union of India, Supreme Court of India. The full text of the Supreme Court decision is available at: <http://supremecourtindia.nic.in/outtoday/patent.pdf>. Ref. Kapczynski, A., ‘Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector’, *Vol. 97 Columbia Law Review* (2010) p.1592.

impact in terms of accessibility and affordability of Gleevec in developing countries, as the price difference between the originator and generic versions of the drug is striking.<sup>34</sup>

From the perspective of essential health innovation, Section 3(d) and its application in the Novartis case also have the long term impact in terms of moving away from the manipulative use of patent as a market tool, and rethinking the essence of innovation.

### *Experimental Use Exceptions*

Research or experimental use exception is one of the key flexibilities allowed under the TRIPS agreement. India Patent Act establishes experimental and research use exception through two provisions. Section 107(2) of India Patent Act states that ‘making, using, importation and distribution’ of patent for the purpose of Section 47 would not be considered as infringement.<sup>35</sup> Referring to Section 47(s) such exploitation of patent could be done ‘for the purpose merely of experiment or research including the imparting of instruction to pupil’.<sup>36</sup>

However, it has been commented that the two provisions have been drafted in an ‘extremely complicated manner’.<sup>37</sup> Accordingly, the provisions do not provide clear definition on research and experiment, also do not provide a distinction between commercial and non-commercial use as such.<sup>38</sup> These might be some of the common problems with research use exception in national laws.<sup>39</sup> Nonetheless, rooms for interpretation and judicial application of the provisions remain.

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<sup>34</sup> Kantarjian, H., et al., ‘The Price of Drugs for Chronic Myeloid Leukemia (CML); A Reflection of the Unsustainable Prices of Cancer Drugs’, *Blood* (April 25, 2013), available at:

<http://bloodjournal.hematologylibrary.org/content/early/2013/04/23/blood-2013-03-490003.full.pdf>.

<sup>35</sup> Section 107(2), India, Patent Act, amended up to 2005.

<sup>36</sup> Id.

<sup>37</sup> Nagarsheth, A., ‘Experimental Use Exception: An International Comparative Overview with a Possible Answer to the Forthcoming India Patent Legislation’, *Vol.9 Journal of Intellectual Property Rights* (2004), p.554.

<sup>38</sup> Id.

<sup>39</sup> Rodrigues, E B. Jr., *The General Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development*, (Cambridge University Press, 2012), p.187.

### *NGO Activism in Patent Law Reform Process*

It has been observed that India civil society becomes aware of the issue of intellectual property and its impact on development in a fairly early stage.<sup>40</sup> As a pioneer organization, Lawyers Collective in India has started conducting national survey and launched the program specifically looking at the impact of drug patent on health in 2001, before the Patent Act 1970 started its further revision in 2005.<sup>41</sup> In addition to activists actions of petition and demonstration calling for public health friendly patent reform, India civil society also adopted a more organized approach to resistance through litigations. After the 2005 Patent Law revision, nearly 20 patent oppositions have been launched by civil society organizations on pharmaceutical patents.<sup>42</sup> Instead of working on patent as a standalone issue, it has been incorporated as an integral part of the advocacy strategy by many groups.<sup>43</sup> Using litigation is also a resistance through formal platform, the same one where Novartis would appeal for its patent rejection or challenge the legality of India patent law.

Having achieved the level of success in terms of greater awareness and support in safeguarding the validity of Sec 3(d) under the new Patent Law, civil society movement also faces the same pressure of increasing expansion of patent regime through bilateral and multilateral trade negotiations. While the impact on national patent law is in a forum where resources and strategies could be mobilized more locally, the bilateral and multilateral trade negotiations would pose more alien and new challenges to India civil society in its continued journey on access to medicines.

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<sup>40</sup> George, J., et.al. 'Intellectual Property and Access to Medicines: Development and Civil Society Initiative in India' ed., *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, (Rio, 2009), p.129.

<sup>41</sup> Id. p. 130.

<sup>42</sup> Id. p. 132-133. The number of opposition cases should have been increased to date, while the citation only counted the number up to 2009.

<sup>43</sup> Id. p.133.

## PATENT GIANT OR INNOVATION ANXIETY?: CASE OF CHINA

China has become a country with the largest number of patent filing in the world.<sup>44</sup> However, it remains arguable to claim China as a country with high level of innovation by merely looking at the quantitative patent data. Nonetheless, China has been observed as in the aspiration of transforming from an ‘imitation oriented country to an innovation oriented country’.<sup>45</sup>

From the view of industry and market scale, it has been noted that, the pharmaceutical market in China has an annual growth at 14% for the past two decades,<sup>46</sup> and has become the world’s fifth largest pharmaceutical market.<sup>47</sup> According to statistics from the State Food and Drug Administration, in 2007, there were 6913 pharmaceutical manufacturers in China<sup>48</sup>. As the world’s second largest producer of pharmaceutical ingredients,<sup>49</sup> China also sees the market size of 439 million USD of its vaccine sector.<sup>50</sup>

### *Three Revisions of Patent Law and the Relevance to Health Innovation*<sup>51</sup>

Chinese patent law was first issued in 1985 and has been revised for three times to date. The revision in 1992 was undertaken against the background of a US-China bilateral memorandum of understanding on intellectual property protection. Two critical changes adopted in this revision in relation to health. Firstly, the revision prolonged the patent term from 15 to 20

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<sup>44</sup> Reuters, China Tops US, Japan to become Top Patent Filer, December 21, 2011, available at: <http://www.reuters.com/article/2011/12/21/us-china-patents-idUSTRE7BK0LQ20111221>.

<sup>45</sup> Id.

<sup>46</sup> Id., p.25.

<sup>47</sup> Id.

<sup>48</sup> The Whitepaper of Drug Safety Supervision of China, July 18, 2008, State Food and Drug Administration; available at: [http://news.xinhuanet.com/health/2008-07/18/content\\_8567782.htm](http://news.xinhuanet.com/health/2008-07/18/content_8567782.htm).

<sup>49</sup> Grace, C., ‘The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines’, *Issue Paper, DFID Health Resource Centre*, (London, 2004), p.14.

<sup>50</sup> Li, Y., *Imitation to Innovation in China: The Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham, Edward Elgar, 2010), p. 26. See also, Liu, Y J. & Wang, N., ‘Vaccine in China: Advances in Biopharmaceutical Technology in China’, *BioPlan Associates, Inc. and Society for Industrial Microbiology*, (2006), 9(22).

<sup>51</sup> The content of this section was updated and modified based on the author’s publication in 2009. Hu, Y Q., *et.al.* ‘Multi-sector Approaches on Improving Access to ARVs in China’, in Brazilian Interdisciplinary AIDS Association and Ford Foundation (ABIA) ed., *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, (Rio, 2009), pp. 82-110.

years starting from the date of filing. Secondly, although methods of medical diagnosis and treatment were kept non-patentable, the 1992 revision opened the door to granting product patent on pharmaceuticals, three years prior to the entering into effect of TRIPS agreement in 1995.<sup>52</sup> Because the 1992 revision was made earlier than TRIPS, China could not be benefited from the transitional arrangement regarding product patent on medicines when it entered into the WTO in 2000.

Chinese patent law completed its third revision in December 2008 following a few normative developments of TRIPS regime, including the Doha declaration on TRIPS Agreement and Public Health adopted in 2001<sup>53</sup>, the Decision on Implementation of Paragraph 6 of Doha Declaration issued in 2003<sup>54</sup> by the WTO General Council,<sup>55</sup> as well as the protocol amendment on TRIPS adopted in 2005<sup>56</sup>. The third revision of the Chinese patent law integrated a number of flexibility mechanisms that would benefit the access to medicines. For instance, it strengthened the mechanism of compulsory license by incorporating the Paragraph 6 system endorsed by the WTO protocol amendment allowing compulsory licences to be issued on the request from another developing country with insufficient manufacture capacities on pharmaceuticals. In addition, the amendment also introduced the parallel import<sup>57</sup> mechanism which would help gain space of choices in mitigating the price disadvantage on medicines.

### *Research Exception Clause*

The current patent law contains a number of exceptional provisions. Firstly, Article 69 (4) of China's Patent Law excludes research and experimental use of patent without authorization

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<sup>52</sup> Ref. Article 27.1 of TRIPS.

<sup>53</sup> WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Doha, November 20, 2001, available at: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>54</sup> WTO General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, Geneva, August 30, 2003, available at: [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm).

<sup>55</sup> Id.

<sup>56</sup> WTO General Council, Amendment of the TRIPS Agreement, WT/L/641, Geneva, 8 December 2005, available at: [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm).

<sup>57</sup> Article 69(1), China, Patent Law, amended up to 2008, available at: [http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119\\_566244.html](http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html).

from being considered as infringement.<sup>58</sup> However, the wording of this clause has been criticised as over-simplified, and would potentially raise misunderstanding on the scope of exception entitled under the provision.<sup>59</sup> Essentially, the meaning of ‘specific for the purpose of scientific research and experiment’<sup>60</sup> has been interpreted through judicial review as only applicable when the research is specifically targeted on the patent concerned itself, but not related research and experiment with using the patent.<sup>61</sup> Such restrictive interpretation would be problematic for the purpose of conducting follow-up innovations.

### *Dilemma around Patentability Criteria on Pharmaceuticals*<sup>62</sup>

Patentability criteria for pharmaceutical products are specified in the examination guideline of China, which was issued by the State Intellectual Property Office (SIPO) for patent examiners. Two aspects of the current patentability criteria would be discussed in relation to access to medicines. Firstly, China adopted absolute novelty test standard during the third revision of Patent Law in 2008. Accordingly, any form of disclosure of the invention regardless of geographic locations would form prior art.<sup>63</sup> This amendment not only strengthened the novelty requirement for inventions, but also provided a refined interpretation of prior art. Such move has been seen as beneficial for domestic innovations,<sup>64</sup> and to improve quality of patent in general.

The second aspect is the patentability for derivative forms of the basic pharmaceutical molecules. Differentiating from the approach under India Patent Law, China has a more relaxed patentability for this type of subject matter. For instance, Chinese patentability criteria

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<sup>58</sup> Article 69 (4): ‘The following shall not be deemed to be patent right infringement:...(4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation’, China, Patent Law, amended up to 2008.

<sup>59</sup> Hu, X., ‘Weakness and Proposal for Improvement on the Research and Experimental Use Exceptions under Chinese Patent Law’, 15 November, 2011, available at (Chinese only): [http://private11.bjss23.host.35.com/Web\\_P/N\\_Show/?PID=5873](http://private11.bjss23.host.35.com/Web_P/N_Show/?PID=5873).

<sup>60</sup> Article 69(4), China, Patent Law, amended up to 2008.

<sup>61</sup> Id.

<sup>62</sup> This section was referred based on the author’s publication in 2009. Hu, Y Q., *et.al.* ‘Multi-sector Approaches on Improving Access to ARVs in China’, in Brazilian Interdisciplinary AIDS Association and Ford Foundation (ABIA) ed., *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, (Rio, 2009), pp. 82-110.

<sup>63</sup> Article 22, 24, China, Patent Law, amended up to December 2008.

<sup>64</sup> Li, Y., *Imitation to Innovation in China: The Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham, Edward Elgar, 2010), p. 121.

allow combinations of chemical compounds to be patentable. In August 2006, GSK made a global announcement of withdrawing one patent application in India and Thailand on its pharmaceutical product Combivir, a combination of single drug 3TC and AZT that is used for treating HIV/AIDS.<sup>65</sup> However, since GSK holds the patent on the basic combination of 3TC and AZT in China, the case of accelerating generic production became irrelevant.

Nonetheless, some of the recent jurisprudences of patent disputes have shed light on the potential retreat of patentability issue. Comparing with the doctrine under Section 3(d) of India Patent Act, Chinese patentability does not preclude derivative forms of known subject matters to be patentable. The forms of salt, polymorph, isomers and ester all have potentials of getting patent granted. Nonetheless, one recent re-examination ruling has showed a different scenario. The case concerns patent invalidation on the drug TDF, used for both HIV/AIDS and Hepatitis B treatment and with Gilead as the original patent holder. The invalidation decision from the patent re-examination commission of SIPO was made on the ground of lacking of inventiveness of the patent in the form of salt derived from a basic molecule.<sup>66</sup> It is hard to assess the extent to which persuasive references had been taken by the re-examination panel to the invalidation and rejection judgments made in other countries on the same medicine, such as Brazil and India.<sup>67</sup> Up to the time of the research, the decision is still open for appealing. However, it presented a vague gesture of rethinking patentability criteria in the Chinese context.

### *NGO Involvement in Patent Law Reform Process*

Comparing with India, the overall development of NGO remains a new phenomenon in China. In the context of access to medicines and patent, the awareness of such issue had not emerged until after the government programme on HIV/AIDS treatment launched in 2003. In addition,

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<sup>65</sup> Third World Network, GSK Withdraws Combivir Patent Application From India And Thailand, September 12, 2006, available at: [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/twn.ipr.info.090603.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.090603.htm)

<sup>66</sup> IHS, China's SIPO Declares Gilead Sciences' Viread Patent Invalid, July 25, 2013, available at: <http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065981446>.

<sup>67</sup> Ref. Patent Opposition Database, TDF Portfolio, available at: <http://patentoppositions.org/drugs/4f1081fb04a7f937af000019>



differentiated from India where the cultivation of patent knowledge and legal awareness were largely done through self-initiative among local organizations, Chinese NGO started knowing of patent through interaction and technical capacity building from international NGOs.<sup>68</sup> In the context of policy advocacy through internal expert lobbies, international NGOs remain the major force in submitting commentaries and suggestions.<sup>69</sup> Over years, local advocacy has started using formal political channel for petition through the National People's Congress.<sup>70</sup> While collective actions remain rare, Chinese NGO has so far not utilized litigation as an organized strategy of resistance.

With awareness and knowledge increased among Chinese activists working on health issues, the level of engagement on patent specific discussion is still in developing. One challenge facing Chinese NGO is the general legal and political environment in the country. Political advocacy might be conceived as a level of social instability and thus get suppressed. In addition, the common challenge of tackling the increasing globalization of intellectual property through trade talks is also shared by Chinese NGOs. With the country moving towards more liberal economic model with increasing trade venues, the issue of intellectual property remain a focus by major trading partners, such as US and EU countries. The extent to which Chinese NGO will be able to play a bigger role in extending the resistance to patent as a barrier to access to medicines is a question open for further observation.

## CONCLUSION

The challenge of improving access to medicines in the context of global expansion of patent through TRIPS and trade liberalization remains. With the global resistance to patent presents as a form of politicization of patent law, the national movement and its interaction with patent law reform further presented the forum of resistance and the bargaining for consistence with

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<sup>68</sup> Hu, Y Q., *et.al.* 'Multi-sector Approaches on Improving Access to ARVs in China', in Brazilian Interdisciplinary AIDS Association and Ford Foundation (ABIA) ed., *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, (Rio, 2009), pp. 88.

<sup>69</sup> Id. p.90.

<sup>70</sup> Id. p.91-92.

international norms at local level. The cases of China and India present similar yet different approaches in handling such pressures and tensions through law reform, by integrating common norms with keeping spaces of national discretions.

Regarding the functions of flexibilities of patent system, both patentability criteria and research use exception are analysed. Patentability is an important discretion for national law. The case of India demonstrated how a tailored design of patentability could foster the development of its domestic pharmaceutical industry and local R&D capacity. By the contrast, China has adopted a more liberal approach to patentability which allow wider scope of subject matter to be patentable including derivative forms of known medicines, which has caused considerable barrier for the country to facilitate access to affordable essential medicines. With the expansion of global patent system through TRIPS, India has revised its patent law yet with discretion on patentability remain especially that concerns Section 3(d) of Patent Act in preventing secondary patenting. Nonetheless, while India's effort might sustain in the short period in order to preserve its generic capacity, the questions of its longer term impact on incremental innovation is still open for discussion. In addition, as both countries are still under external pressure to adopt more rigorous intellectual property system in general, the future prospect of patentability discretion remains uncertain.

The research or experimental use exception is another form of flexibility under patent system aiming to foster innovation. Both China and India patent laws include provisions allowing research and experimental use to be exempted from infringement judgement. However, research has identified some common shortcomings of regulating such exception, including the unclear definition and interpretation that might risk of obstructing research activities as commercial ones and make such exceptional provisions dysfunctional. This criticism is applicable to Chinese and Indian laws. In China, research exception is vaguely enacted. The judicial interpretation has adopted a restrictive approach which might block the research use for relevant innovations impossible. In India, the clause in the new law has also been criticized as being ambiguous, more precise interpretations are needed.

During the process of patent reform in both countries, the involvement of local civil societies has plays important role in gaining legitimacy of the law reform. Such involvement is also part

of the global social movement on access to medicines and intellectual property. Although NGOs face substantively different legal and policy environment, development history and technical capacities in China and India, a number of formal forums of resistance have been used respectively. While India NGO developed organized strategy of litigation as a formal forum of resistance and pressure, Chinese NGO started using formal political channel to voice its concern. In addition, the challenges of responding to the multiplied forums of patent expansion are shared in common among NGOs in both China and India.

The analysis of the above mentioned aspect has also revealed a fundamentally shared challenge facing at national level, which is the ability of counter balance with the continuous expansion of global patent system marked by TRIPS and TRIPS-plus requirements under the regional and bilateral trade negotiations. Such expansion has contributed potentially to a pro-patent culture among in countries as China and India. The future prospect of the law reform and social movement would continue to be a set of resistance at different levels, and the possibilities of softening such resistance would largely depend on political wills in trade negotiations, and the possibility for international community to work out an alternative mechanism on medical innovation so that the deadlock of patent war could be solved.